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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,127	03/31/2004	Ashish A. Patel	G-33712P1	9219

1095 7590 10/02/2007

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
PURDY, KYLE A	

ART UNIT	PAPER NUMBER
1609	

MAIL DATE	DELIVERY MODE
10/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/815,127	PATEL ET AL.	
	Examiner	Art Unit	
	Kyle A. Purdy	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August, 15, 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1 sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Claims 1-29 are pending and claims 1-29 are presented for examination on the merits. The following rejections are made.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bess et al. (US 6,359,011) in view of MacLaren et al. (US 6,039,974) and Ortyl et al. (US 5,738,872) and ~~in~~ further view of Tanno et al. (US 6,559,134).

4. The claims of the instant application are drawn to a pharmaceutical composition in the form of a bilayer tablet comprising two discrete portions having formulation A and formulation B. Formulation A is drawn to a sustained-release of a sympathomimetic drug, specifically pseudoephedrine, present in an amount of 120 mg, wherein said drug is comprised within a carrier material, said carrier material comprises a mixture of: (i) a filler (about 1% to about 30% by weight); (ii) a cellulose binder (about 10% to about 60% by weight); (iii) ethylcellulose (about 5% to about 50% by weight); (iv) a wax (about 2% to about 50% by weight); and (v) a lubricant (about 0.1% to about 3% by weight). Formulation B is drawn to a rapidly released piperidinoalkanol compound, specifically fexofenadine and pharmaceutically acceptable salts

thereof, present in an amount of 60 mg, wherein said drug is comprised within a carrier material, said carrier material comprises a mixture of: (i)' a sugar (about 10% to about 70% by weight); (ii)' a disintegrant (about 1% to about 40% by weight); and (iii)' a lubricant (about 0.1 % to about 3% by weight).

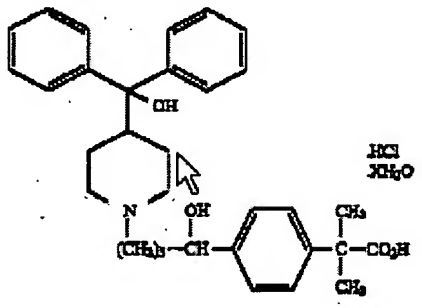
5. Bess et al. ('011) teaches a pharmacetucal composition which contains a denaturant for sympathomimetic amine salts in the form of a tablet consisting of an additional ingredient to prevent the conversion of psuedoephedrine to the illegal substance methamphetamine (see Abstract). It is stated that sympathomimetic amines like that of pseudoephedrine induces vasoconstriction in the vascular bed of the nasal mucosa resulting in the shrinking of the engorged mucous membranes with the physiological result of improved air flow and increased drainage (see column 5, lines 59-65).

6. '011 teaches several examples of a composition including the sympathomimetic amine, pseudoephedrine. In particular, example H teaches a composition which includes a filler, a cellulose binder, a cellulose binder, a lubricant and a wax which are lactose, hydroxyethyl cellulose, ethylcellulose, magnesium stearate and stearic acid, respectively (see column 14, lines 29-53). The weight percentages for each of these are as follows and are based upon the masses given for each (according to Example H): lactose ~10%; hydroxyethyl cellulose ~3.5%; ethylcellulose ~10%; magnesium stearate ~0.6%; and stearic acid ~3.5%. It is also disclosed that the invention of '011 includes that of sustained-release formulations (see column 10, lines 15-24).

7. Bess et al. lacks the teaching of a bilayer tablet containing a second discrete layer comprising fexofenadine carried by a sugar, disintegrant, and lubricant combination (see above for weight percentages).

8. MacLaren et al. ('974) teach a pharmaceutical composition that is a combination of piperidinoalkanol-decongestant wherein the composition is in the form of a bilyar tablet comprising two discrete zones having formulations A and B (see Abstract). Formulation A is drawn to a sustained release composition comprising a decongestant (i.e. sympathomimetic drug), specifically that of psuedoephedrine which is present in an amount 120 mg (see column 2, lines 32-40 and Table 1. Formulation B of '974 is drawn to an immediate release composition comprising a piperidinoalkanol compound, specifically that of 4-[4-[4-(hydroxydiphenylmethyl)-1-piperdinyl]-1-hydroxybutyl]-α, α-dimethylbenzeneacetic acid (i.e. fexofenadine) which is present in an amount of 60 mg (see column 2, lines 32-40 and Table 1). Fexofenadine is known to be useful as an antihistamine, antiallergic agent and a bronchodilators, and is slightly soluble in water. Example 5 of '974 meets most of the general requirements for the fexofenadine formulation of the instant application as the mixture contains, among other ingredients, a sugar, a disintegrant, and a lubricant which are microcrystalline cellulose, croscarmellose sodium, and magnesium stearate, respectively.

9. Ortyl et al. ('872) teach a pharmaceutical composition containing piperidinoalkanol compounds. The invention of '872 provides a pharmaceutical composition wherein the piperidinoalkanol used is fexofenadine which has the following structure:



10. Suitable combinations of inert ingredients in combination with fexofenadine according to '872 include microcrystalline cellulose, pregelatinized starch, gelatin, magnesium stearate, calcium carbonate and sodium starch glycolate, in amounts of from about 20% to about 85%, 5% to about 50%, 1% to about 15%, 0.05% to about 3%, 5% to about 50%, and 1% to about 15% (see column 13, lines 47-52). However, it is disclosed at column 13, lines 15-46 that binders can be selected from pregelatinized starch, cellulose derivatives including methyl cellulose, carboxymethyl cellulose, hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), sucrose and the like. It is noted that '872 does not specifically recite these previous excipients as "disintegrants" but rather as "binders", however, HPC is inherently a binder and a disintegrant as evidenced by Applicants identification of HPC as such (see [0013] and [0047] of instant application).

11. Table 5 of '872 discusses the preferred amounts of inert ingredients for the fexofenadine containing composition. Example #5 of Table 5 teaches the weight percentages for the following: microcrystalline cellulose is about 26%, lactose is about 26% and magnesium stearate is about 0.75%. The teaching does not specifically disclose hydroxypropyl cellulose but referring back to column 13, lines 26-30 of '872 where microcrystalline cellulose is taught to be a functionally equivalent it would an obvious substitution to replace pregelatinized starch with that

of HPC and doing so would provide an excellent starting point from which one skilled in the art could begin formulations.

12. Tanno et al. ('134) teaches solid preparations containing low-substituted hydroxypropyl cellulose (HPC). It is stated that the use of HPC is to provide a formulation where the preparation rapidly dissolves in the oral cavity. It is stated that dosages taking this form are useful because they can be tailored for the aged or the infant (see column 1, lines 20-23). The low-substituted hydroxypropyl cellulose taught by '134 contains a hydroxypropyl group in an amount of 5 to 16% wt.% (see column 3, lines 46-57). Further, column 4, lines 24-33, stated that low-substitued HPC should preferably make up between 5 and 50% wt.% in a solid preparation because a content less than 1% will cause the tablet to have insufficient strength whereas a content more than 99% will cause a delay in disintegration as the tablet will be to strong (see column 4, lines 23-30).

13. Thus, it would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to have prepared a pharmaceutical composition comprising two discrete formulations comprising an antihistamine and a decongestant, as taught by MacLaren et al., because doing so would provide a dosage which would have the desired effects of providing simultaneous relief of congestion and cough and other symptoms of allergies. Moreover, as the teachings of the references are within similar fields of endeavor, it would have been obvious to one in the art to combine them and arrive at a conventional dosage form with the properties of the instant invention. Therefore, it would be obvious to one in skilled in the art to combine the teachings of Bess et al. with MacLaren et al. and Ortyl et al. with more than a reasonable expectation for success.

14. It would have been obvious to one of ordinary skill in the art to use low-substituted HPC in combination with the references teachings discussed above in order to provide a formulation that dissolves rapidly to provide immediate relief via fexofenadine of allergies. Moreover, one would have a reasonable expectation for success in using low-substituted HPC rather than HPC, because substitution of one known element for that of another would yield predictable results, and thus should not be given any patentable weight. The teachings of Bess et al. when combined with MacLaren et al. and Ortyl et al. in view of Tanno et al. meet all of the limitations of the instantly claimed invention. Therefore, it would be obvious to one in skilled in the art to combine the teachings of Bess et al. with MacLaren and Ortyl et al, in view Tanno et al. with more than a reasonable expectation for success.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Ardin Marschel and Cecilia Tsang, can be reached on 571-272-0718 or 571-272-0562, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kyle A. Purdy
Examiner

CECILIA TSANG
SUPERVISORY PATENT EXAMINER